



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/603,705 | 06/25/2003 | Kent Harrison | 10527-454001 | 3440 |
| 26161 | 7590 | 03/03/2006 | EXAMINER | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | JOHNSON III, HENRY M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3739 | |
| DATE MAILED: 03/03/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/603,705 | Applicant(s) HARRISON, KENT | |
| | Examiner Henry M. Johnson, III | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-18, 23, 24, 35, 36, 38-41 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-18, 23, 24, 35, 36, 38-41 and 43-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>010306</u> | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. While the examiner believes the prior art could read on the claims based on size being a design choice (A change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).), alternative art has been selected to specifically address the size issues. Swanson teaches an apparatus for procedures within a heart with longitudinal deployment and access via the femoral artery. The use of the Boyd et al. pad is an obvious alternative to the cooling used by Swanson. The arguments relating to the applicant's important new cooling application is unpersuasive as none of the claims address any unique structure or methods steps relating to the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, 35, 38, 40, 44 and 46-47 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2004/0215177 to Swanson. Swanson discloses catheter-based probes used to create lesions typically include a relatively long and flexible catheter body that supports a cryogenic element at or near its distal end. The portion of the catheter body that is inserted into the patient is typically from 60 to 140 cm in length and

Art Unit: 3739

there may be another 20 to 40 cm, including a handle, outside the patient. The length and flexibility of the catheter body allow the catheter to be inserted into a main vein or artery (typically the femoral vein) and directed into the interior of the heart such that the cryogenic element contacts the tissue that is to be ablated (paragraph 0040). Introducer sheaths and introducer ports are used to introduce catheters and surgical probes into the body. Introducer sheaths have a relatively long body that may extend through the insertion area to the target tissue region (paragraph 0042). The introducer is interpreted as the elongated body and the catheter with cooling element is deployed longitudinally from the distal end of the sheath. Swanson teaches the cooling may be a cryogenic element, such as a balloon or hollow metal tip, is carried on the distal end of a catheter or surgical probe placed in contact with tissue and cooled. The cryogenic element may be cooled by a variety of techniques. One technique employs the Joule-Thompson effect. The cryogenic element may also be cooled by directing super-cooled fluid through the catheter or surgical probe to the cryogenic element (paragraph 0005). Swanson discloses a catheter with infusion and ventilation lumens that may be used for delivery of cooling medium (paragraph 0047).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 36, 39, 41, 43 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0215177 to Swanson as applied to claims 1, 35 and 40 above, and further in view of U.S. Patent 5,799,661 to Boyd et al.

Art Unit: 3739

Swanson is discussed above, but does not teach a cooling patch with sleeve and internal cooling channels. Boyd et al. teach devices and methods for cardiac surgery including a device for cooling tissue comprising an elongate shaft (Fig. 42, # 233) with a deployable cooling structure at its distal end (Fig. 42, # 231), delivered to the treatment site via a sheath (Fig. 42, # 239). The sheath is retracted to deploy the cooling structure, this movement interpreted as deploying the cooling structure in a longitudinal direction. The flexible heat exchanger (231) is collapsible to a pre-deployed position that can easily fit through an access port (introducer sheath). The flexible heat exchanger is attached to the distal end of an elongated tubular shaft (catheter of Swanson). An inflow lumen (234) extends through the tubular shaft and is fluidly connected to the flexible heat exchanger. A return lumen (235) extends through the tubular shaft parallel to the inflow lumen. The lumens may be formed integrally with the tubular shaft. The proximal ends of the inflow lumen and the return lumen are adapted for attachment to a circulating pump and a reservoir of cooling fluid (Col. 21, lines 5-25). The flexible heat exchanger is interpreted as a patch and the shaft is longitudinally movable with the sheath. The flexible heat exchanger is made from two sheets of flexible plastic, which are heat-sealed, or RF sealed together to form a serpentine cooling path (232) through the heat exchanger. Preferred materials for manufacturing the flexible heat exchanger 231 include polyurethane, vinyl, polypropylene, nylon, etc. The flexible heat exchanger may have a flexible backbone (frame), which extends from the distal end of the tubular shaft to the distal edge of the heat exchanger. The flexible backbone may be made from a flexible polymer, elastomer, or a resilient metal wire, such as spring temper stainless steel or a superelastic nickel/titanium alloy, or a composite of metal and plastic. The flexible heat exchanger is rolled, folded or twisted and placed in an introducer sheath 239 in the pre-deployed position (Col. 21, lines 25-41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the

Art Unit: 3739

deployable flexible heat exchanger as taught by Boyd et al. in the device and methods of Swanson as Swanson specifically teaches alternative cooling elements as usable with the sheath and catheter.

Claims 10-17, 23, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0215177 to Swanson in view of U.S. Patent 5,799,661 to Boyd et al. Both are discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the deployable flexible heat exchanger as taught by Boyd et al. in the device and methods of Swanson as Swanson specifically teaches alternative cooling elements as usable with the sheath and catheter.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0215177 to Swanson in view of U.S. Patent 5,799,661 to Boyd et al. Swanson and Boyd et al. disclose the claimed invention except for dual patches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an additional patch, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,799,661 to Boyd et al. in view of U.S. Patent 6,514,245 to Williams et al. Boyd et al. are discussed above, but do not teach the use of gas expansion or the Joule-Thompson effect for cooling. Williams et al. disclose a cryotherapy catheter where the cooling fluid may pass through a Joule-Thompson orifice (Col. 14, lines 44-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a Joule-Thompson orifice as taught by Williams et al. in the device of Boyd et al. because it is a well known methodology for cooling in medical devices. Those skilled in the art would look to related

Art Unit: 3739

inventions in the cryotherapy for structures and methodologies for implementation, providing the motivation for such a combination.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2004/0215177 to Swanson in view of U.S. Patent 5,799,661 to Boyd et al. and further in view of U.S. Patent Application Publication US 2004.0030259 to Dae et al. Swanson and Boyd et al. are discussed above, but do not teach a temperature sensor near the heat exchange area. Temperature sensors are well known and pervasive in the art as evidenced by the sensor of Dae et al. (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a temperature sensor as taught by Dae et al. in the device of Swanson in view of Boyd et al. to monitor the process of cooling.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

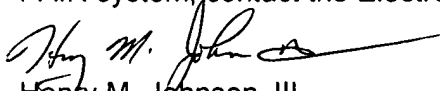
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Primary Examiner
Art Unit 3739